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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/389,545 09/03/99 DUNSTAN

C A-605

021069
AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS CA 91320-1799

HM12/1106

EXAMINER

HELMS, L.

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/389,545

Applicant(s)

DUNSTAN, COLIN R.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and the election of species B in Paper No. 10 is acknowledged. The traversal is on the ground(s) that restriction of Groups I and II to different species of cancer therapy would place upon the Applicants undue burden. This is not found persuasive because as stated in the restriction requirement the species are distinct. As to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group and species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-22 have been canceled.

Claims 23-40 have been added.

Claims 23-40 are under examination with the species chemotherapy.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action

4. The following Office Action contains some NEW GROUNDS of rejection necessitated by amendment.

Specification

5. The disclosure is objected to because of the following informalities:
- a. Page 45 has a reference to a co-pending application but the application number is not stated .
- Appropriate correction is required.

Claim objection

- 6.. Claim 40 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend on a multiple dependent claim. See MPEP § 608.01(n).

Response to Arguments

7. The rejection of newly added claims 23-40 under 35 USC 112 second paragraph is maintained.

The response filed 9/19/01 has been carefully considered but is deemed not to be persuasive. The response states "new claims 22-39 particularly point out and distinctly claim the subject matter" (see page 7 of response). In response to this argument, the amended claims still encompass the indefinite nature of the phrase "lytic bone disease" which as previously stated is not clear what bone loss disturbances can be defined by the phrase "lytic bone disease".

8. The rejection of newly added claims 23-30, 35-40 35 U.S.C. 112, first paragraph is maintained and made again.

The response filed 9/19/01 has been carefully considered but is deemed not to be persuasive. The response states that unfused OPG could be used to prevent and treat bone loss as evidenced by Table 1 in WO 97/23614. In response to this argument the response is partially correct in that the reference only demonstrates 22-401 of unfused human OPG and only unfused OPG of residues 22-194, 22-200, 22-293, and 22-355 of mouse. The claims encompass any OPG of any residues as well as any truncated polypeptides of OPG. In addition, claim 30 encompasses OPG fused to any polypeptide and the specification only enables a Fc Δ C-OPG(22-194) fusion protein for treating bone loss. The specification does not enable prevention of loss of bone or abnormal bone formation. In addition, the response does not address the unpredictability in the art as evidenced by Lodish et al and Sternson with regards to protein delivery and prevention.

9. The rejection of newly added claims 23-40 under 35 USC 103(a) as being unpatentable over Boyle et al (WO/9723614) and further in view of Conte et al (Annals of Oncology 5:S41-S44, 1994) or Simonet et al (Cell 89, 309-319, 1997) in view of Conte et al is maintained and made again.

The response filed 9/19/01 has been carefully considered but is deemed not to be persuasive. The response states "the examiner has not pointed out any suggestion in the references to administer an OPG polypeptide and a cancer therapy agent for treating bone loss due to cancer" (see page 6 of response). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is

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noted that the features upon which applicant relies (i.e. treatment of cancer,) are not recited in the rejected claim(s) of 23 and those that depend on claim 23. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Guens, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, both the Boyle et al and Simonet et al references teach OPG as a bone loss inhibitor associated with any disorder characterized by bone loss (see page 36 of Boyle et al and page 317, last lines prior to Experimental procedures in Simonet et al) and Simonet et al specifically teach utility of OPG in metastatic malignancy (see cite above). The Conte reference specifically teach a combination of a chemotherapeutic agent and a bone loss inhibitor. As stated previously, one would have been motivated by the obvious advantage of inhibition of bone loss with inhibition of the cancer metastasis as taught by Conte et al.

10. All other rejections of record are withdrawn in view of the amendments to the claims.

Conclusion

11. No claim is allowed

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,
Larry R. Helms Ph.D.
703-306-5879


SHEELA HUFF
PRIMARY EXAMINER